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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/225,502	01/06/1999	PAUL A. MOORE	PF392	2400

22195 7590 05/05/2003

HUMAN GENOME SCIENCES INC
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EXAMINER
DECLOUX, AMY M

ART UNIT	PAPER NUMBER
1644	73

DATE MAILED: 05/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/225,502	MOORE ET AL.	
	Examin r	Art Unit	
	Amy M. DeCloux	1644	

-- The MAILING DATE f this c mmunication appears on the cover sheet with the c rresp ndence address --

Peri d f r R ply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 February 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-56 and 58-103* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-56 and 58-103* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2-11-03, Paper No. 32, has been entered.

Response to Amendment

In view of said amendment, the outstanding 112 second paragraph rejection has been withdrawn. However, the utility rejection and its associated 112 first enablement rejection have been maintained. Applicant is correct in their belief that the 112 first paragraph written description rejection of claims 38-51 and 68-80 were withdrawn in Paper No. 30.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

MAINTAINED Claims 21-56 and 58-103 are rejected under 35 U.S.C. 101 because the claimed invention lacks a credible, substantial, specific, or well-established utility.

MAINTAINED Claims 21-56 and 58-103 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Response to Arguments

Applicant's arguments filed 2-11-03 have been fully considered but they are not persuasive. Applicant traverses the rejection on the grounds that the present asserted utility of binding FK506 is not implausible to one of skill in the art based on the sequence homology with FKBP65 which binds FK506, and the presence of conserved PPIase domains present in all other FKBPs and the presence of seven conserved amino acid residues shared among all other FKBP's that have been identified, these residues thought to be involved in FK506 binding interactions.

This is not found persuasive because Applicant has not shown that the recited proteins actually bind FK506, but only speculate the presence of this property in the polypeptides set forth as SEQ ID NO:s 6 and 8 based on sequence homology. Applicant contends that the FKBP65 protein disclosed in the Coss et al manuscript was believed to be a member of the FKBP family based on sequence homology and the presence of PPIase domains. However the examiner notes that the last sentence of the Abstract of said article states that the results "suggest" that FKBP65 is a new FKBP family member, not "shows" or "demonstrates".

However, even if said polypeptides bind FK506, and are in fact a member of the FKBP family, the function or utility will not have been established. The Coss et al article attached to the Applicant's amendment filed 4-29-02, comments on the functional diversity of FKBP family members, and that though at the time of its publication FKBP65 was identified as a member of the FKBP based on sequence homology (the presence of three PPIase domains), the possible functions of FKBP65 were still unknown (see entire article, especially the last two paragraphs of the article).

Applicant contends that said functional diversity taught by Coss is related to the differences in FKBP's subcellular location and association with various intracellular complexes, and is mechanistic information which is not required for satisfying utility under 101. Applicant further contends that said differences in location or intracellular interactions does not change the fact that FKBP binding to FK506 leads to immunosuppression by inhibiting T cell proliferation and or differentiation, or that FKBP PPIase activity is inhibited by such binding. Applicant further states that the instantly recited SEQ ID NO:s 6 and 8 contain four PPIase domains and that PPIase domains contain two regions within said domains that appear to be important for binding FK506. Applicants further contend that based on this homology, it is more likely than not that said sequences are in fact novel members of the FKBP family and that they do bind FK506, and that because FK506 binding proteins (FKBP) are established and useful proteins, assignment of the instant SEQ ID NO:6 and 8 imputes the same well established utility.

However the examiner notes that said Coss article states in column 2 of the first page of the article that the inhibition of PPIase activity in itself does not appear to be responsible for the immunosuppressant effect of the drug. The examiner also notes that the specification discloses that the instantly claimed proteins binds FK506 based on sequence homology, and does not disclose that said binding of said instantly claimed proteins to FK506 leads to immunosuppression by inhibiting T cell proliferation and or differentiation. In view of the potential divers intracellular interactions, one could envisage multiple functions for said proteins. However, the examiner notes that being a family member based on sequence homology alone does not show function, as evidenced by the wide range of functions exhibited by the immunoglobulin family of proteins. absent evidence to the contrary.

Claim Objections

Claim 38 is objected to because of the following informalities: the word "or" in part (a) of claim 38 is unclear, perhaps the word "of" was intended. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

A) Claims 29-30, 43-45, 72-74, 85-87, 59-61, and 95-97 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The instant claims are drawn to a nucleic acid molecule that is heterologous to SEQ ID NO:5 or 7, or a nucleic acid molecule that encodes a polypeptide that is heterologous to SEQ ID NO:6 or 8. However, the instant specification discloses no heterologous sequences of said nucleic acid molecules or polypeptides, other than said sequences which are all from homo sapiens. Therefore, the invention encompassing heterologous sequences such as those from other species is not adequately described. *see University of California v. Eli Lilly and Co. 43 USPQ2d 1398.*

B) Claims 37, 51, 67, 80 and 103 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The instant claims are drawn to a composition comprising nucleic acid and a pharmaceutically acceptable carrier, wherein said nucleic acid encodes a FKBP65-like protein. The instant specification discloses that FKBP65 is a FK506 binding protein and confers immunomodulating activity to FK506, rapamycin and cyclosporin A, (Page 6, lines 20-26 of the instant specification). Identifying a protein as having homology to FKBP65, does not indicate what function it and thus the encoding polynucleotide might have. In order for the claim to be enabled, the specification must teach how to make the claimed composition without undue experimentation and must teach how to use the composition for at least one pharmaceutical use without undue experimentation. There is no specific disease or specific function that is suggested by this homology; no conserved regions that would indicate that the claimed polypeptides function similarly to FKBP65 are identified. Therefore, it would require undue experimentation to predict which diseases could be treated using a pharmaceutical composition comprising the recited nucleic acid.

Conclusion

No Claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy M. DeCloux whose telephone number is 703 306-5821. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 703 308-3973. The fax phone numbers for the organization where this application or proceeding is assigned are 703 872-9306 for regular communications and 703 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-0196.

Amy DeCloux, Ph.D.,
Patent Examiner,
April 28, 2003

Patrick J. Nolan, Ph.D.
Primary Patent Examiner,
Group 1640